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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,907	06/30/2000	RUDI WILFRIED JAN PAUWELS	07619.0006	4853

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PATRICIA A. KAMMERER
HOWREY SIMON ARNOLD & WHITE, LLP
750 BERING DRIVE
HOUSTON, TX 77057-2198

EXAMINER

GARCIA, MAURIE E

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 04/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/530,907

Applicant(s)
Pauwels et al

Examiner
Maurie E. Garcia, Ph. D.

Art Unit
1627



-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-36 and 38-62 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-36 and 38-62 are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other: _____

DETAILED ACTION

1. There appears to be some confusion as to the pending claims in the instant case. Please note the following. Applicant's Preliminary Amendment filed with the instant case cancels claims 37 and 41-44 and amends claims 1, 2, 4-12, 14, 15, 17-20, 22, 24, 27, 29, 32, 33, 36 and 38. New claims were also added (See paragraph 3 below).
2. First, the case contains an Article 34 amendment that was not entered in the case. This non-entry was communicated to applicant in the PCT 905 form mailed on May 31, 2000. This amendment contains claims numbered 31-44. Again, these claims have not been entered in the instant case. Thus the cancellation of claims 41-44 that was referred to in the Preliminary Amendment has not been done, as these claims are not a part of the instant case. Claim 37, however, has been cancelled as per applicant's request and claims 1, 2, 4-12, 14, 15, 17-20, 22, 24, 27, 29, 32, 33, 36 and 38 have been amended as well.
3. Therefore, due to the above reasons, the numbering of claims is not accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. The newly added claims that applicant has designated as 45-68 have been renumbered. Specifically, misnumbered claims 45-68 have been renumbered as claims 39-62.

4. Therefore, the currently pending claims are (1) originally numbered 1-36 & 38 (as amended in the Preliminary Amendment) and (2) renumbered claims 39-62, i.e. 1-36 and 38-62.

Election/Restriction

5. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

6. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention from the following groups to which the claims must be restricted.

- I. Claims 1-36 and 38-41, drawn to a method for the rapid screening of analytes.
- II. Claims 42-52, drawn to a device for dispensing liquid.
- III. Claims 53-62, drawn to a method of dispensing liquid.

7. The inventions listed as Groups I – III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons that follow.

8. There does not appear to be a technical feature that links all of the claims as there are two different methods and a device claimed (see paragraphs 10-13 below).

Moreover, the method of Group I is known in the art as disclosed by Virtanen (US 6,342,349). This reference is described below. Thus the instant Groups I – III lack unity.

9. Virtanen discloses assay devices and methods based on optical disks, where “analyte-specific signal elements are disposed on an optical disk substrate” (See Abstract). The assays of Virtanen also use “cleavable signal elements”, see column 5, lines 49-66 and Example 2 in columns 71-72. See especially the assay method described in column 6, lines 11-25.

10. Note that if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c). The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

11. Moreover, see MPEP 1850: Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By “dependent” claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression “category of claim” referring to the classification of claims according to the subject

matter of the invention claimed, for example, product, process, use or apparatus or means, etc.).

12. Also note 37 CFR § 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage, cited in part below.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

13. The instant application does **not** contain combinations of categories of invention set forth in paragraph (b) above. The application instead contains multiple distinct methods and a device (see sections (c) and (d) above). Thus, for all of these reasons, the instant claims lack unity of invention.

14. This application contains claims directed to more than one species of the generic invention for Group I. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 (see paragraphs 16-18 below). The species are set forth as follows.

15. If applicant elects the invention of **Group I**, applicant is required to elect from the following patentably distinct species. Please elect one species from *each* subgroup below.

Species of solid support

Applicant is required to elect, for purposes of search, a specific species of solid support from those set forth in the claims. For example, solid support is a detector; solid support is a film or tape; solid support is a compact disk, etc.

Species of analyte (e.g. claim 29)

Applicant is required to elect, for purposes of search, a specific species of analyte to be screened.

Species of semi-solid or liquid medium

Applicant is required to elect, for purposes of search, a specific species of semi-solid or liquid medium.

Species of target (e.g. claim 33)

Applicant is required to elect, for purposes of search, a specific species of target.

16. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons.

17. PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". It further defines "special technical feature" as "those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art". For example, unity of invention is fulfilled if:

- (a) all alternatives have a common property; **and**
- (b) (i) a common structure is present, i. e. a significant structural element is shared by all alternatives, or
- (b) (ii) in cases where the common structure can not be the unifying criterion, all alternatives belong to a recognized class of compounds in the art to which the invention pertains. (MPEP 1850).

18. In the instant case, part (a) above is not fulfilled because all claimed species do not have a common property (i.e. different physical and/or chemical characteristics). Further, all of the species do not belong to a recognized class in the art to which they pertain. Moreover, the claimed method is known in the art, see paragraphs 8 & 9 above. For these reasons, election under these rules is proper and required.

19. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

20. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

21. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

23. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).


24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:30 to 7:00 and alternate Fridays.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

26. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot

program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Maurie E. Garcia, Ph.D.
April 19, 2002



MAURIE E. GARCIA, PH.D
PATENT EXAMINER